

SPECIFICATION

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10 **UTERINE CONTRACTION DETECTION AND INITIATION
 SYSTEM AND METHOD**

BACKGROUND OF THE INVENTION

 The present invention is generally directed to a
15 system and method for effecting uterine contractions of an
 animal. The present invention is more particularly directed
 to such a system and method for detecting and automatically
 stimulating contractions of the uterus of a human.

 Prolonged pregnancy, generally classified as a
20 gestational age exceeding 42 weeks of gestation, is associated
 with increased perinatal morbidity and mortality.
 Specifically, in addition to the increased neonatal deaths,
 there is an increase in the meconium aspiration, depressed
 infant at five minutes, and cesarean section rate. The
25 mortality from meconium aspiration can be as high as 38% for
 those women managed expectantly.

 Electrical energy applied to the myometrium or uterine
 muscle has been proposed to affect uterine contractions. One
 system and method to this end is disclosed in Karsdon, U.S.
30 Patent Nos. 5,447,526 and 5,713,940 which are incorporated
 herein by reference. In accordance with a preferred

5 embodiment disclosed in these patents, a first or positive
electrode is placed in surface contact to a woman's abdomen
over the top of the uterus. Four negative electrodes are
placed in spaced apart relation in surface contact to the
woman's abdomen over lower portions of the uterus beginning at
10 approximately a mid portion of the uterus. The negative
electrodes and the positive electrode are then connected to a
muscle controller which generates square wave pulse trains of
current between the positive electrode and the negative
electrodes. The muscle controller is capable of providing
15 current pulse trains of selectable polarity. The controller
is activated to inhibit uterine contractions when they are
undesirably present or to initiate uterine contractions when
they are undesirably absent.

In accordance with a further embodiment disclosed in the
20 above-referenced Karsdon patents, a uterine contraction
monitor is added to the system with feedback to the
controller. The monitor is disposed for surface contact with
the abdomen. The amount of electrical energy applied is thus
responsive to the sensed contractions. The feedback may be
25 negative or positive depending upon whether contraction
initiation or inhibition is desired.

5 While the contraction monitor of Karsdon represents a
significant step forward in the prenatal management of
patients, there remains substantial room for improvement. The
contraction monitor disclosed in the Karsdon patents is a
surface monitor. Such monitors respond to physical movement.
10 As a result, physical movement which is a certainty to occur
other than that of real contractions will also be sensed and
create a noisy signal environment in which the contraction
affecting device must respond. It would be most advantageous
to have a contraction monitor which is substantially more
15 specific in detecting uterine contractions.

Further, surface monitors must be worn in order to
function. Hence, if a patient is to be constantly monitored,
the monitor must be worn at all times. This would include
times of sleep and other times when such use would either be
20 inconvenient, cumbersome, or confining.

In addition, there is no guarantee that such a surface
monitor will remain in the same place or that if removed, it
will be returned to the same location on the body at a later
time. This can result in signals which are variable in
25 amplitude and other characteristics making the application of
threshold criterion difficult.

5 Hence, there is a need in the art for an improved
uterine contraction detection and stimulation system to
initiate uterine contractions. More specifically, such a
system must be capable of providing detection signals of good
quality, in a low noise environment, and specific to uterine
10 contractions. This would assure that stimulation to initiate
uterine contractions will be provided when actually needed and
not be provided when such stimulation is not required. The
present invention provides such an improved uterine
contraction detection and stimulation system.

15

SUMMARY OF THE INVENTION

20 The invention therefore provides a method of detecting
for uterine contractions and stimulating a uterus of an animal
having a body to initiate uterine contractions when uterine
contractions are absent. The method includes the steps of
placing first and second electrodes in contact with the body,
the first electrode being placed in direct contact with the
uterus, sensing electrical activity between the first and
second electrodes, detecting for uterine contractions from the
25 sensed electrical activity, and providing electrical current
flow between the first and second electrodes when uterine
contractions are undetected.

5 The invention further provides a system for detecting
for uterine contractions and stimulating a uterus of an animal
having a body to initiate uterine contractions when uterine
contractions are absent. The system includes a first
electrode, a first anchor for anchoring the first electrode to
10 the uterus of the animal, and return current path establishing
means for establishing a return current path within the body,
the return current path including the first electrode. The
system further includes a sense amplifier coupled to the first
electrode for sensing electrical activity of the body, a
15 detector coupled to the sense amplifier for detecting for
contractions of the uterus from the sensed electrical activity
and a source of electrical energy coupled to the first
electrode and responsive to the detector failing to detect
uterine contractions for providing electrical energy to the
20 body along the return current path for initiating contractions
of the uterus.

 The invention still further provides a system for
detecting for uterine contractions and stimulating a uterus of
an animal having a body to initiate uterine contractions when
25 uterine contractions are absent wherein the system includes
first and second electrodes for establishing a return current
path within the body, an anchor for releasably anchoring at

5 least one of the electrodes to the uterus of the animal, a
detector coupled to the first and second electrodes for
detecting for uterine contractions, and a source of electrical
energy responsive to the detector failing to detect uterine
contractions for applying electrical energy to the first and
10 second electrodes for initiating contractions of the uterus.

The present invention further provides a system for
detecting for uterine contractions and stimulating a uterus of
an animal to initiate contractions when uterine contractions
are absent, the system including a sensor for sensing
15 electrical activity of the uterus, a processor for analyzing
the electrical activity of the uterus, and an energy source
for applying electrical energy to the uterus responsive to the
processor when the electrical activity of the uterus fails to
satisfy predetermined detection criteria.

20 The invention further provides a system for detecting
for uterine contractions and stimulating a uterus of an animal
to initiate contractions when uterine contractions are absent,
the system including a sensor for sensing electrical activity
of the uterus, means for storing data associated with the
25 sensed electrical activity of the uterus, a processor for
analyzing the stored data, and an energy source for applying
electrical energy to the uterus to initiate contractions of

5 the uterus responsive to the processor when the analyzed data fails to satisfy predetermined detection criteria.

The invention further provides a method of detecting for uterine contractions and stimulating a uterus of an animal to initiate uterine contractions when uterine contractions are
10 absent. The method includes the steps of sensing electrical activity of the uterus, analyzing the electrical activity of the uterus, and applying electrical energy to the uterus to initiate contractions of the uterus when the analyzed electrical activity of the uterus fails to satisfy
15 predetermined detection criteria.

The invention still further provides a method of detecting for uterine contractions and stimulating a uterus of an animal to initiate uterine contractions, wherein the method includes the steps of sensing electrical activity of the
20 uterus, generating data associated with the sensed electrical activity, storing the data associated with the sensed electrical activity; analyzing the stored data, and applying electrical energy to the uterus to initiate contractions of the uterus responsive to the analyzed data failing to satisfy
25 predetermined detection criteria.

BRIEF DESCRIPTION OF THE DRAWINGS

The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

Figure 1 is a side view, partly cut away, of a pregnant patient and a system for detecting and initiating uterine contractions having a pair of electrodes in direct contact with the patient's uterus in accordance with a preferred embodiment of the present invention;

Figure 2 is a schematic diagram of a uterine contraction detection and initiation unit embodying further features of the present invention;

Figure 3 is a partial side view to an enlarged scale and partly in cross section illustrating a first step in placing an electrode in direct contact with a uterus of a patient;

Figure 4 is a partial side view to an enlarged scale and partly in cross-section illustrating a further step in placing an electrode in direct contact with a uterus of a patient;

5 Figure 5 is a partial side view to an enlarged scale and partly in cross-section illustrating an electrode in direct contact with the uterus of a patient in accordance with a preferred embodiment of the present invention; and

 Figure 6 is a side view, partly cut away of a pregnant
10 patient and another uterine contraction detection and initiation system embodying the present invention.

DETAILED DESCRIPTION

Referring now to Figure 1, it schematically illustrates
15 a pregnant patient 10 having a uterus 11 and a fetus 12 disposed within the uterus 11. The uterus 11 is enclosed by the abdominal wall 18 of the patient and includes an amniotic cavity 14 which is defined by the uterine wall 15. The uterine wall 15 is primarily comprised of the uterine muscle
20 or myometrium 16. As is well known, the fetus 12 is disposed within amniotic fluid contained within the amniotic cavity 14.

 In accordance with the present invention, a system 19 detects for and initiates contractions of the uterus 11. More specifically, the system 19 includes a detection and
25 initiation unit 20 including a uterine contraction detector 31 and a source of electrical energy 33. The system 19 further includes first and second leads 22 and 24 having first and

5 second electrodes 26 and 28 respectively. The first and
second electrodes are coupled directly to the uterus 11 to
establish a current return path between the electrodes within
the myometrium 16. As will be seen with respect to Figure 2,
the electrodes 26 and 28 are coupled to both the detector 31
10 and energy source 33 of unit 20.

As can be clearly seen in Figure 1, the electrodes 26
and 28 of leads 22 and 24 respectively are in direct contact
with the myometrium 16. The electrodes 26 and 28 are also
preferably configured so as to be releasably anchored within
15 the myometrium 16 as will be more particularly described
subsequently.

In the detection of contractions of the uterus 11, the
electrodes 26 and 28 provide an electromyographic signal (EMG)
representing the electrical activity of the myometrium 16.
20 Because the electrodes 26 and 28 are within the myometrium 16,
the EMG is very specific to the electrical activity of the
myometrium 16. When the EMG satisfies a predetermined
criteria to be explained subsequently, uterine contractions
are determined to be present. Conversely, when the EMG fails
25 to satisfy a predetermined criteria, uterine contractions are
considered to be sufficiently absent to require uterine
stimulation for uterine contraction initiation.

5 When contractions of the uterus 11 are to be initiated,
the electrical energy source 33 is activated by the detector
31 to provide, for example, trains of square wave voltage
pulses. The electrical energy is applied directly to the
myometrium 16 along the aforementioned current return path
10 within the myometrium by virtue of the electrodes 26 and 28
being directly in contact with the myometrium 16. Because the
electrodes 26 and 28 are fixedly anchored within the
myometrium 16, they will not be dislodged by the uterine
contractions to enable the therapy to have its complete
15 therapeutic effect. However, because the electrodes are
releasably anchored, they may be readily removed in a non-
invasive manner when no longer needed.

To lend further understanding of the present invention,
the electrical activity of the uterus can exhibit two distinct
20 forms of activity. One form is that of a uterine contracture
which is exhibited long before actual labor. Contractures are
represented by bursts of electrical activity which can last on
the order of several minutes and which are widely spaced apart
by separations of about an hour or more. Contractures are
25 disorganized muscle activity of the myometrium causing
minimal, if any, physical manifestations of the myometrium.

5 The other form is that of a uterine contraction.

Contractions are represented by relatively short bursts of electrical energy with the bursts being relatively closely spaced apart. For example, during labor, the uterine contraction electrical bursts of energy may have durations of
10 thirty seconds or less with separations on the order of twenty minutes or less. Contractions, as compared to contractures, are organized muscle activity of the myometrium causing pronounced physical manifestations of the myometrium. It is the occurrence of contractions that is most identified as
15 labor.

The electrical energy bursts of both contractures and contractions are made up of electrical waves having separations of, for example, three hundred milliseconds to nine hundred milliseconds (300ms to 900ms). As will be seen
20 subsequently, one or more characteristics of the EMG electrical bursts are used to identify actual contractions or the lack thereof in need of initiation.

Referring now to Figure 2, it illustrates in schematic form, the uterine contraction detection and initiation unit 20
25 of Figure 1. The unit 20 includes the contractions detector 31 and energy source 33 within an enclosure 30. The unit 20 is turned on by a switch 50 which connects a battery 51 to the

5 various components of the unit 20 when contractions are to be initiated or maintained.

Within the enclosure 30 is also a microprocessor 32 which, in a manner well known in the microprocessor art, operates on operating instructions stored in an internal
10 memory 52 or an external memory (not shown). As a result of such operation, the microprocessor 32 implements the contractions detector 31 including burst duration stage 39, a first timer 41, an inhibit stage 45 and a second timer 47. Also, stored in memory portion 53 of memory 52, are
15 preprogrammed contraction detection parameters or criteria.

The contraction detector 31 further utilizes a sense amplifier 35 and a threshold circuit 37. The sense amplifier 35 has a pair of inputs which are coupled to outputs 68 and 70 of the unit 20. The outputs 68 and 70 are adapted to be
20 coupled to the first and second electrodes 26 and 28.

The electrodes 26 and 28 provide the EMG representing the electrical activity of the myometrium. The EMG is amplified by the sense amplifier 35. The amplified EMG is then provided by the sense amplifier 35 to the threshold
25 detector 37. Whenever an electrical wave from the sense amplifier 35 exceeds a threshold magnitude set by the

5 threshold detector 37, the threshold detector will provide an output to an interrupt input 43 of the microprocessor 32.

The burst duration stage 39 time stamps each interrupt input and stores each time stamp in memory 52. It also, with timer 41, starts keeping time from each interrupt input. When
10 the timer 45 has timed a predetermined time period of, for example, five seconds without being reset by another interrupt, the burst duration stage 39 considers the current burst to be completed. The next interrupt will then represent the beginning of the next burst of electrical activity.

15 The inhibit stage 45 precludes the energy source 33 from stimulating the uterus as long as contractions are sufficiently present. To that end, the second timer 47 starts keeping time from the beginning of each burst as determined by the duration stage 39. As long as the second timer 47 is
20 reset by the burst duration stage 39 before it times out, the inhibit stage 45 will continue to inhibit the energy source 33. However, when a next burst fails to begin within the time out time period of the second timer 47, the inhibit stage 45 activates the energy source 33 for stimulating the uterus to
25 initiate the next contraction. The time out period of timer 47 may be, for example, on the order of two minutes. As a result, if a next burst does not occur within two minutes of

5 its immediately preceding burst, the beginning the contraction
detector 31 will consider the contractions to be insufficient
and warranting uterine stimulation to initiate the next
uterine contraction. Hence, a new contraction will be
initiated when a uterine contraction is undetected within a
10 predetermined time from the beginning of an immediately
preceding uterine contraction. As can be appreciated by those
skilled in the art, the time out period may be tailored to an
individual patient. The above time out period is provided as
being exemplary only.

15 The energy source 33 includes a charging circuit 34, an
analog to digital converter 36, a storage capacitor 38, and an
H bridge 40 comprising field effect transistors 42, 44, 46,
and 48.

The electrical energy source 33 is activated by the
20 inhibit stage 45 of the contractions detector 31 over a line
49 which causes the charge circuit 34 to charge capacitor 38.

The memory 52 has storage locations 54, 56, 58, 60, and 62
for storing preprogrammed energy delivery parameters such as
pulse voltage, pulse polarity, burst duration, pulse interval,
25 and pulse duration respectively. The foregoing parameters
including the detection parameters may be stored in the memory

5 52 with a programming computer (not shown) of the type well known in the art.

The charge circuit 34 charges the storage capacitor 38 to the pulse voltage programmed at memory location 54. The output of the charge circuit 34 is monitored by the analog to
10 digital connector 36 which provides the microprocessor with a digital representation of the output voltage of the charge circuit 34. In this manner, the microprocessor is capable of regulating or controlling the charge circuit 34 to maintain the preprogrammed pulse voltage across the capacitor 38.

15 The H bridge 40 is of the type well known in the art which is controlled by the microprocessor 32 over control lines 64 and 66 which are provided with buffers 65 and 67 respectively to accommodate required voltage swings and higher voltage applied to H bridge 40. The signals provided by the
20 microprocessor over the control lines 64 and 66 cause the energy source 33 to provide a train of output pulses at the output terminals 68 and 70 having the pulse polarity, burst duration, pulse interval, and pulse duration as preprogrammed in memory locations 56, 58, 60 and 62 respectively of the
25 memory 52. The output terminals 68 and 70 of the unit 20 are coupled to the leads 22 and 24 respectively as shown in Figure

5 1 to provide the electrodes 26 and 28 with the preprogrammed electrical energy.

Figures 3-5 illustrate a manner in which the electrodes 26 and 28 may be substantially non-invasively placed in direct contact with the uterus 11 through the abdomen 18 and more particularly in direct contact with the myometrium 16 in accordance with a preferred embodiment of the present invention. Referring first to Figure 3, there is illustrated, to an enlarged scale, the abdominal wall 18 and the myometrium 16. The abdominal wall includes the skin 72 and the abdominal muscle 74.

In an initial step, a removable inner needle 76 is first inserted into an introducer tube 78. The introducer tube 78 terminates in a conical surface 80 which matches the terminating conical surface 82 of the removable inner needle 76. With the conical surfaces 82 and 80 aligned as shown in Figure 3, the introducer tube 78 and removable inner needle 76 are moved in unison to pierce the skin 72 and abdominal muscle 74. Movement of the introducer tube 78 and removable inner needle 76 is terminated when the tip 84 of the needle 76 has entered the space 86 between the abdominal muscle 74 and myometrium 16 to such an extent that the conical surface 80 of the introducer tube 78 is within the space 86. Once the

5 removable inner needle 76 and introducer tube 78 are
positioned as shown in Figure 3, the removable inner needle 76
is withdrawn from the introducer tube 78. With the removable
inner needle 76 thus removed from the introducer tube 78, the
introducer tube 78 is now ready to receive the electrode 26 at
10 the distal end of its lead 22 as illustrated in Figure 4.

The lead 22 has a cylindrical lead body with an inner
electrical conductor 23 which contacts a conductive collar 25
of the electrode 26. The electrode 26 has a structure 27
secured to the collar 25 by welding, for example. The
15 structure 27 is formed of a relatively rigid conductive wire
29 configured as a screw-in tip. More specifically, the
electrode structure 27 is formed in the shape of a helix so
that when the lead 22 is introduced through the introducer
tube 78 to an extent permitting the electrode 26 to contact
20 the myometrium 16, rotation of the lead 22 as indicated by the
arrow 88 causes the helical screw-in tip 29 of electrode 26 to
screw into the myometrium 16.

When the lead 22 has been rotated a sufficient number of
turns to fully embed the electrode tip 29 within the
25 myometrium 16, the lead will be securely, but releasably,
anchored within the myometrium 16. This is illustrated in
Figure 5 where it can be seen that the helical tip 29 of the

5 electrode 26 is fully embedded within the myometrium 16. Once
this is accomplished, the introducer tube 78 may be removed to
thus render the lead 22 passing through the abdominal wall 18
including the skin 72 and abdominal muscle 74 with the
electrode 26 securely anchored to the uterus 11 and more
10 specifically, the myometrium 16. As a result, during the
therapy of initiating contractions of the uterus 11, the
contractions of the uterus 11 will not dislodge the electrode
26 from the myometrium 16. However, when therapy is no longer
required and the electrode 26 is no longer needed, it may be
15 readily withdrawn by just rotating the lead 22 in a direction
opposite that shown at 88 in Figure 4 and pulling the lead
from the patient when the tip 29 is disengaged from the
myometrium.

Referring now to Figure 6, it illustrates a further
20 embodiment of the present invention. Here it may be seen that
the unit 20 is coupled directly to the myometrium through the
lead 22 and electrode 26 as previously described while another
lead 90 couples the unit 20 to a surface of the body of the
patient 10 with a surface or patch electrode 92. The patch or
25 surface electrode 92 is in surface contact with a posterior
portion of the body of the patient 10 and more specifically,
on the back of the patient. With such an arrangement, a

5 return current path is established between the electrodes 26
and 90. The electrical energy from the energy source 33 of
the unit 20 will remain concentrated in the myometrium given
the large surface area of electrode 92 compared to electrode
26. The fetus 12 and the body of the patient 10 will only be
10 exposed to dispersed energy which will be well within safe
limits for both the fetus 12 and mother 10.

While particular embodiments of the present invention
have been shown and described, modifications may be made, and
it is therefore intended to cover in the appended claims all
15 such changes and modification which fall within the true
spirit and scope of the invention.